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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,378	10/25/2000	John Jianhua Chen	S63.2-9503	2980

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
HON, SOW FUN	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 09/696,378	**Applicant(s)** CHEN ET AL.
	Examiner Sow-Fun Hon	**Art Unit** 1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/23/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,31,33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,31,33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Withdrawn Rejections

1. The 35 U.S.C. 103(a) rejections in the Office action dated 10/08/03 have been withdrawn due to the new rejections below.

Rejections Repeated

2. The provisional obviousness-type double-patenting rejection of claims 1-7, 14, 24-36 over US Application 09/885568 has been repeated for the same reasons of record in the Office action dated 10/08/03.

Appeal Brief

3. Reinstatement of the appeal brief is postponed in view of the new grounds of rejection below.

New Rejections

Claim Rejections – 35 USC § 102

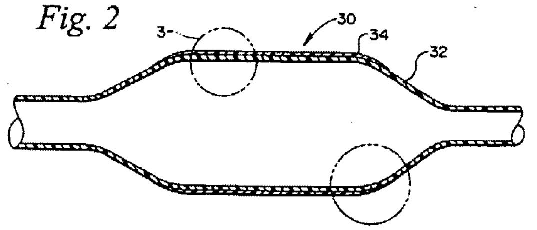
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 12-14, 19, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rau et al. (WO 95/18647).

Regarding claims 1, 24, Rau et al. has a balloon catheter (column 1, lines 1-5) which can be of integral catheter shaft/balloon construction (column 14, lines 1-5) comprising a plurality of

fibers to provide reinforcement (column 8, lines 55-65). The balloon has a longitudinal axis as seen in Fig 2 below. The fibers (filaments) are aligned parallel along the balloon (structure) (column 15, lines 5-10) which is interpreted to mean that the fibers are oriented parallel to the longitudinal axis of the balloon.

Fig. 2



Rau et al. teaches that the balloons have wall thicknesses of about 8 microns to 80 microns (0.0003 – 0.003 inches) (column 11, lines 1-5). The fibers (filaments) are aligned parallel along the balloon (structure) (column 15, lines 5-10) and are embedded in the wall (column 16, lines 10-15). Hence the fibers have diameters smaller than the wall thickness, and in the range of less than 8 microns on the low end of the scale or less than 80 microns on the higher end of the scale, which qualifies them as micro-fibers as defined by Applicant's specification (filed 10/25/00). Applicant defines the micro-fibres as typically having a diameter between 10-12 microns (Specification filed 10/25/00, page 7, lines 1-5). This qualifies the composite as a micro-composite. The reinforcement provides for a dimensionally stable balloon.

Regarding claim 2, Rau et al. teaches a balloon catheter (abstract). Thus the balloon is mounted on a catheter.

Regarding claims 12-14, Rau et al. teaches that the reinforcing fiber may comprise liquid crystal polymers (column 15, lines 1-5) (claim 14), and that liquid crystal polymers are rigid, rod-like (column 16, lines 25-30) (claim 12). Rau et al. teaches that any other polymer material having a rod-like molecule, which imparts a tendency to align more readily during melt flow,

may be used (column 17, lines 5-10). Thus the polymer material is thermoplastic (flows during melt) and may be semi-rigid-rod (claim 13).

Regarding claim 19, Rau et al. teaches that the matrix component comprises a thermoplastic polyimide which forms an inflatable balloon (column 10, lines 15-20). Thus the thermoplastic polyimide is semi-compliant, being able to inflate, yet hold a shape.

Claim Rejections - 35 USC § 103

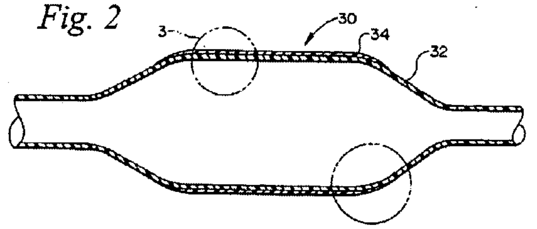
6. Claims 31, 33, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. (WO 95/18647).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Regarding claim 31, Rau et al. teaches that the balloon is inflatable (column 7, lines 1-5) (claim 31). The matrix component comprises a thermoplastic polyimide which forms an inflatable balloon (column 10, lines 15-20). Thus the thermoplastic polyimide is semi-compliant, being able to inflate, yet hold a shape. Rau et al. teaches that the reinforcing fiber may comprise liquid crystal polymers (column 15, lines 1-5) (claim 14), and that liquid crystal polymers are rigid, rod-like (column 16, lines 25-30). Being rigid, the liquid crystal core polymeric material has a bulk elongation less than the matrix material when oriented in the direction of the longitudinal axis. For good reinforcement, or strengthening of the matrix, it

would have been obvious to one of ordinary skill in the art to provide liquid crystal polymer fibres which are stronger than the matrix material, and operatively adhere to the matrix material for good load transfer.

Fig. 2



Regarding claim 33, Fig. 2 of Rau et al. above shows a balloon designed for radial expansion, not longitudinal expansion. Thus a balloon which longitudinally expands less than 5 % beyond its pre-inflation state is the result of routine experimentation.

Regarding claim 36, Rau et al. teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30). Thus it has a multilayer structure.

6. Claims 3-8, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. as applied to claims 31, 33, 36 above, and further in view of Zdrahala (previously cited US 5,248,305).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Regarding claims 3-7, Rau et al. fails to teach the specific amounts of the liquid crystal polymer fibril/ thermoplastic blend.

Zdrahala teaches a catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness where both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5). The composition contains from 5 to 35 weight percent of the liquid crystal polymer fibril (column 5, lines 20-30) which overlaps the claimed range of about 0.1 to about 20 weight percent (claim 3) the narrower range of 0.5 to about 15 % (claim 5) and the narrowest range of 0.5 to about 8 % (claim 4); the balance of the composition being the 95 to 65 weight percent of the polymer base (matrix) component, which overlaps the claimed range of from about 99.9 to about 50 % (claim 6) and the narrower range of 99.5 to about 85 % (claim 7).

Regarding claim 8, Rau et al. fails to teach the inclusion of a melt compatibilizer.

Zdrahala teaches that a surfactant may be provided (column 5, lines 25-30). A surfactant acts as a compatibilizer for two unlike components.

Regarding claims 25-26, Rau et al. fails to teach that the liquid crystal polymer fibers are oriented diagonally relative to the longitudinal axis of the balloon, and changes through the balloon material in a direction transverse to said longitudinal axis.

Zdrahala teaches that the liquid crystal fibers are distributed in the matrix material helically relative to the balloon axis (separate phase of liquid crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15). This means that the fibers are oriented

diagonally relative to the longitudinal axis of the balloon (claim 25), changing through the balloon material in a direction transverse to said longitudinal axis (claim 26).

Zdrahala teaches that the catheter tubing is for use in percutaneous transluminal coronary angioplasty (PCTA) ('305, column 1, lines 15-20). Rau et al. teaches that the balloon catheter is used in angioplasty ('647, column 1, lines 1-5). Zdrahala provides the specifics for the process of forming the liquid crystal polymer fibril/thermoplastic catheter tubing ('305, column 6, lines 35-40) and thus provides the motivation to use it for the formation of the tubular parison of Rau et al., in order to obtain a balloon catheter where the reinforcing liquid crystal polymer fibrils are provided with the desired orientation for use in angioplasty.

7. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. as applied to claims 31, 33, 36 above, and further in view of Zdrahala (previously cited US 5,248,305) as evidenced by Yang (previously cited Polymer Data Handbook).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Rau et al. fails to teach that the liquid crystal polymer (LCP) has a melting point of less than 250 °C.

Zdrahala teaches a catheter tubing comprising liquid crystal fibrils (column 1, lines 1-5) which exhibits stiffness in the longitudinal direction as well as rotational stiffness where both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5).

Zdrahala teaches that the liquid crystal polymer may be hydroxypropyl cellulose (column 4, lines 5-10). It is thermoplastic since it melts, and has the claimed melting point of Applicant, as evidenced by Yang.

Yang provides data showing that hydroxypropylcellulose has a melting point of 208 °C (481 K) (page 137 of the handbook, page 3 of the printout) which is within the claimed range of about 275 °C or less (claim 15), the claimed range of about 250 °C or less (claim 16), the claimed range of about 150 °C to 249 °C (claim 17) and the claimed range of about 230 °C or less (claim 18).

Zdrahala teaches that the catheter tubing is for use in percutaneous transluminal coronary angioplasty (PCTA) ('305, column 1, lines 15-20). Rau et al. teaches that the balloon catheter is used in angioplasty ('647, column 1, lines 1-5). Zdrahala provides the specifics for the process of forming the liquid crystal polymer fibril/thermoplastic catheter tubing ('305, column 6, lines 35-40) and thus provides the motivation to use it for the formation of the tubular parison of Rau et al., in order to obtain a balloon catheter where the reinforcing liquid crystal polymer fibrils are provided with the desired orientation for use in angioplasty.

8. Claims 20, 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al., as applied to claims 31, 33, 36 above, and further in view of Zdrahala, as evidenced by Polymers (previously cited A Property Database).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component

distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Rau et al. fails to teach the claimed melting point of the matrix component.

Zdrahala teaches that the base polymer matrix component of the catheter tubing may be nylon 12, a polyamide (column 4, lines 15-35) which has the claimed melting point of Applicant, as evidenced by Polymers.

Polymers provides data showing that nylon 12 has a melting point range of from 169 °C to 187 °C, which is within the claimed range of about 140 °C to 265 °C (claim 20), the claimed range of about 150 °C to 230 °C (claim 22) and the claimed range of about 220 °C or less (claim 23).

Zdrahala teaches that the catheter tubing is for use in percutaneous transluminal coronary angioplasty (PCTA) ('305, column 1, lines 15-20). Rau et al. teaches that the balloon catheter is used in angioplasty ('647, column 1, lines 1-5). Zdrahala provides the specifics for the process of forming the liquid crystal polymer fibril/thermoplastic catheter tubing ('305, column 6, lines 35-40) and thus provides the motivation to use it for the formation of the tubular parison of Rau et al., in order to obtain a balloon catheter where the reinforcing liquid crystal polymer fibrils are provided with the desired orientation for use in angioplasty.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Zdrahala as applied to claims 31, 33, 36 above, as evidenced by Alger (previously Polymer Science Dictionary).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material

comprising a polymer matrix component and a liquid crystal polymer fibril component distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Rau et al. fails to teach that the matrix component comprises a polyester-polyether block copolymer.

Zdrahala teaches a polyester-polyether block copolymer such as HYTREL for the catheter tubing matrix material, as evidenced by Alger.

Alger defines HYTREL as a polyether-polyester block copolymer (page 255).

Zdrahala teaches that the catheter tubing is for use in percutaneous transluminal coronary angioplasty (PCTA) ('305, column 1, lines 15-20). Rau et al. teaches that the balloon catheter is used in angioplasty ('647, column 1, lines 1-5). Zdrahala provides the specifics for the process of forming the liquid crystal polymer fibril/thermoplastic catheter tubing ('305, column 6, lines 35-40) and thus provides the motivation to use it for the formation of the tubular parison of Rau et al., in order to obtain a balloon catheter where the reinforcing liquid crystal polymer fibrils are provided with the desired orientation for use in angioplasty.

10. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. as applied to claims 31, 33, 36 above, and further in view of Heino et al. (previously cited US 6,221,962).

Rau et al. has been discussed above and teaches the dimensionally stable balloon having a longitudinal axis and composed of a micro-composite material, the micro-composite material comprising a polymer matrix component and a liquid crystal polymer fibril component

distributed in the polymer matrix component, the fibril component having micro-fibers oriented substantially parallel to the longitudinal axis of the balloon.

Rau et al. fails to teach a compatibilizer component in the micro-composite material.

Heino et al. is directed to liquid crystal polymer blends wherein the liquid crystalline polymer forms fibers which orient in the flow direction of the thermoplastic matrix melt, improving the tensile strength and modulus of elasticity of the solidified matrix (column 1, lines 30-35). The compatibilizer (claim 8) for the blends can be a block copolymer (column 3, lines 1-15) (claim 9). An example is ethyl acrylate-eth(yl)ene-glycidyl methacrylate (column 7, lines 55-60) (claims 10-11). Heino et al. teaches that the compatibilizer improves the impact, tensile and flexural strength properties of the blend (column 2, lines 25-30).

Therefore it would have been obvious to one of ordinary skill in the art to have added the compatibilizer of Heino et al. to the liquid crystal polymer fibril/thermoplastic composition of Rau et al. in order to obtain a balloon catheter with improved impact, tensile and flexural strength.

Response to Arguments

11. Applicant's arguments with respect to claims 1-26, 31, 33, 36 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SH
Sow-Fun Hon
05/13/04

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772
5/14/04